

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
BOSTON DIVISION

BIEDERMANN MOTECH GMBH and
DEPUY SPINE, INC.,

Plaintiffs,

v.

ALPHATEC SPINE, INC.,

Defendant.

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Case No.: 06CV11111EFH

Judge Edward F. Harrington

PLAINTIFFS' MARKMAN BRIEF

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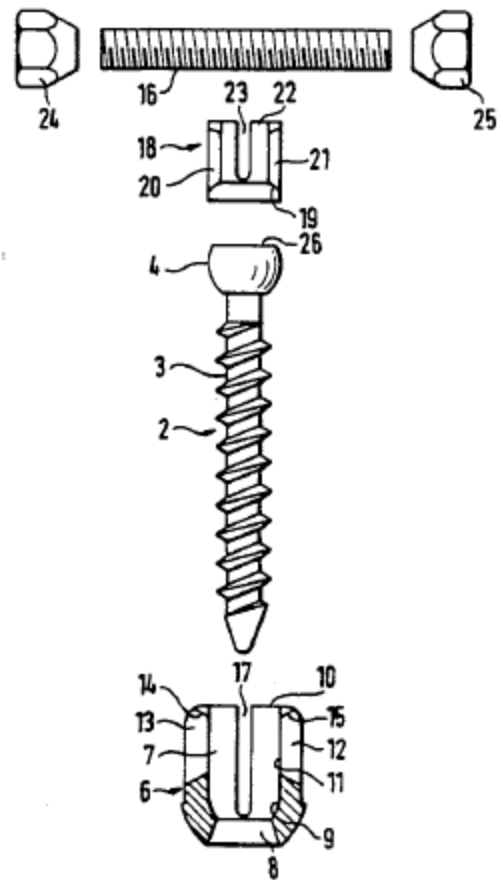
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I. INTRODUCTION

Plaintiffs Biedermann Motech GmbH and DePuy Spine, Inc. (collectively “DePuy”) submit this Markman Brief. Because at this time the arguments of Defendant Alphatec, Inc. (“Alphatec”) have not been fully disclosed, DePuy may seek leave to file an additional brief in response to Alphatec’s brief and/or may seek oral argument on claim construction.

A. The ‘678 Patent

The Court is familiar with the patent in suit, U.S. Patent No. 5,207,678 (“the ‘678 patent”) as the result of having presided over *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, case number 01-cv-10165, so an abbreviated description is included here. The ‘678 patent describes a device for stabilizing spinal column segments comprising a pedicle screw with a spherically-shaped head, a receiver member with holes for receiving a rod and a compression member located between the bottom of the rod and the head of the pedicle screw when the device is assembled. ‘678 Patent (Ex. 1) col. 2, ll. 11-16, 42-44, 50-52 & 58-59.¹ An illustration of one embodiment of these elements is depicted in Figure 1, shown to the right. In this embodiment, a compression member 18 is formed as a cylindrical insert that sits on top of the screw head, below the rod, within the receiver member. (*Id.* at col. 2, l. 58 - col. 3, l. 4.) In that embodiment the rod is threaded, and it is secured to the receiver by nuts that tighten in from the sides. Upon tightening of the nuts, the compression member exerts a compressive force onto the screw head, thus



¹ References to exhibits herein (e.g. “Ex. ____”) are made to the exhibits attached to the Declaration of Patrick J. Norton in Support of Plaintiffs’ Markman Brief.

locking the position of the screw head relative to the receiver. (*Id.* at col. 4, ll. 6-7.)

The '678 patent contains 7 claims, of which claim 1 is the only independent claim. Because of the *Medtronic* litigation and prior claim construction in this case, many claim limitations have already been construed, either by this Court or by the Federal Circuit.

1. Device for stabilizing spinal segments, comprising a pedicle screw (1) having a threaded shaft portion (3) and a spherically-shaped head (4) at the end of said threaded shaft portion, a receiver member (5) **flexibly connected** to said head (4), said receiver member being provided with two **holes for receiving a rod** (16), a receiver chamber (7) being provided within said receiver member (5), the receiver chamber (7) having at one end thereof a bore (8) for passing the threaded shaft portion (3) therethrough and an **inner hollow spherically-shaped portion (9)** for receiving the head (4) of said screw (1), an opening (10) being provided opposite said bore (8) for inserting said screw (1), said device further comprising a **compression member (18) for exerting a force onto said head (4) such that said head is pressed against the hollow spherically-shaped portion (9).**

(*Id.* at col. 4, ll. 9-24; emphasis added.) The six dependent claims 2 through 7 of the '678 patent recite various additional features that may be used within the invention.

B. The Law Governing Claim Construction

The Federal Circuit has repeatedly summarized the basic principles of claim construction, most recently in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). Claim construction begins with the words of the claim. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)(reaffirmed in *Phillips*, 415 F.3d at 1312); *see also Phillips*, 415 F.3d at 1312 (“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which a patentee is entitled the right to exclude.’”). The words of a patent claim are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art. *See Phillips*, 415 F.3d at 1313; *see also Vitronics*, 90 F.3d at 1582.

In determining “the ordinary and customary meanings” of claim limitations, “the claims themselves provide substantial guidance as to the meaning of particular claim terms”; for example, by the context in which a term is used. *Phillips*, 415 F.3d at 1314. In addition, a court will look to the specification to determine whether the inventor has used any terms in a manner

that is inconsistent with their ordinary meaning. *See Vitronics*, 90 F.3d at 1582 (“Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.”), citing *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996). “However, words or expressions of manifest exclusion or explicit disclaimers in the specification are necessary to disavow claim scope.” *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005) (internal quotation marks omitted).

A mere discussion of prior art in the “Background” section of the specification does not serve as a disclaimer of every feature of that prior art. *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006); accord *Brookhill-Wilk, I, L.L.C. v. Intuitive Surgical Inc.*, 334 F.3d 1294, 1300-01 (Fed. Cir. 2003) (in a patent for remote surgery, neither statements in the Objects of the Invention and Background sections of the specification nor disclosure of a single embodiment limited the claim term “remote location” to a place outside the operating room). It is improper to limit the claims of a patent to exactly what is described in the specification and no more. *See Phillips*, 415 F.3d at 1323 (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.”); *Electro Med. Sys., S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1054 (Fed. Cir. 1994) (“[P]articular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments.”); see also *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1341 (Fed. Cir. 1999) (holding that “an attribute of the preferred embodiment cannot be read into the claim as a limitation”).

In addition to the claims and the specification, the court may also consider the prosecution history of the patent if it is in evidence. *Id.* at 1317. The *Phillips* court cautioned, however, that “because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Id.* The Federal

Circuit has also authorized courts to look beyond the “intrinsic evidence” of the claims, specification and prosecution history to consider “extrinsic evidence,” such as dictionaries and expert testimony, but it has cautioned that extrinsic evidence is generally less reliable than the intrinsic record. *Id.* at 1317-18.

II. ARGUMENT

As noted above, pertinent claim limitations of the ‘678 patent have previously been construed. The Federal Circuit’s claim constructions are binding on this Court. *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 494 F. Supp. 2d 54, 60 (D. Mass. 2007) (“Where the Federal Circuit has already construed the claims here disputed, then that higher Court’s construction is binding, and this Court cannot modify its holding.”). This Court’s prior construction of “holes for receiving a rod” in this case, is, of course, binding on Alphatec. (Dkt # 81) (Ex.2.) And this Court’s claim constructions in the *Medtronic* litigation that the Federal Circuit did not expressly address should also be followed here, not just because they were correct, but for the sake of equal treatment of similarly situated parties. In a similar situation, in which the patents in suit had been the subject of earlier litigation involving a different defendant, Judge Young reasoned:

Here, to the extent that this Court has already had the opportunity to construe the language of the claims in the patents at issue and no new arguments have been presented to dispute the previous constructions, fairness requires this court to adhere to the previous constructions. In other words, Roche/Hoffmann [the new defendant] has to come forward with some argument that would alter this Court’s previous claim construction before this Court will modify its previous decision. To do otherwise would be to create the type of ambiguity and uncertainty that *Markman* intended to prevent. *See Markman*, 517 U.S. at 391, 116 S.Ct. 1384.

Amgen, 494 F. Supp. 2d at 60.

A. A “Compression Member” Is An Intermediate Piece (Or Member) That Applies A Compression Force To The Head Of The Screw.

In the *Medtronic* case, this Court construed “compression member” to mean “an intermediate piece (or member) that applies a compression force to the head of the screw.” (Ex. 3 at 13-14.) *Medtronic* had argued that “compression member” was limited to the particular compression member shown in the figures of the ‘678 patent. (*Id.* at 13.) This Court properly

rejected Medtronic's position. (*Id.* at 14-16.) On appeal, the Federal Circuit affirmed this conclusion and held that "compression member" was not a means-plus-function limitation subject to the strictures of 35 U.S.C. § 112, ¶ 6. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1024 (Fed. Cir. 2006). That holding is binding on this Court. *See Amgen*, 494 F. Supp. 2d at 60.

Although Alphatec has not yet proposed a claim construction, in its responses to DePuy's interrogatories, Alphatec has asserted:

The applicants distinguished the compression member in the '678 patent from prior art members that exert non-vertical forces on the head of the screw. *See, e.g., '678 patent*, col. 1:34-53. Thus, the term "compression member" must be construed when a compressing mechanism is present to require that the force exerted thereon be a vertical force and not non-vertical forces.

(Alphatec 3d Supp'l Resps. to Interrogs. at 2.) Alphatec's effort to inject an additional, "only vertical force" limitation into the meaning of "compression member" should be rejected.

The part of the specification to which Alphatec cites in its effort to narrow the Court's and Federal Circuit's definition of "compression member" provides:

The EP 0 242 708 A discloses a pedicle screw consisting of the screw proper having a threaded shaft portion 35 and a spherical or spherical-segment-shaped head and of a receiver member hingedly connected thereto. The receiver member comprises two head halves which are retained by means of a ring and which comprise on their facing inner sides portions formed as segments of a 40 hollow sphere which surround the head in assembled state such that the head is retained in the thus formed hollow sphere allowing a pivoting movement around the center of the hollow sphere. This provides a very well operating pedicle screw. However, in an operation 45 screws of different lengths and eventually also different diameters are required. When using this known screw, it is necessary to have the entire screws in the desired sizes on stock. However, the stocking costs for such complete screws are very high because of the required 50 high precision of the two shell halves having the two spherical-segment-shaped portions and of the ring retaining these parts.

'678 Patent, col. 1, ll. 34-53. In this passage, the inventors of the '678 patent do not even discuss the "compression member" of their invention, let alone distinguish it from so-called "prior art

members.” Indeed, the prior art device that is the subject of this passage did not even include a “compression member.”

The European patent application to which the specification refers is the counterpart of U.S. Patent No. 4,946,458 (“the ‘458 patent”).² (Ex. 4.) As described in the ‘678 patent specification, one of the preferred embodiments of the ‘458 patent included a receiver made up of two halves connected at the bottom in a clam-shell arrangement. *See* ‘678 patent, col. 1, ll. 37-44; *cf.* ‘458 Patent, col. 4, ll. 5-7. That embodiment includes a pedicle screw with a flat top surface that is retained in the receiver member and a rod that passes through the receiver above the top of the screw. In that embodiment, the depth of the slit through which the rod passes “is selected such that the slit ends, in the assembled state shown in FIG. 4 in a distance above the surface 30” of the screw. ‘458 Patent (Ex. 4) at col. 4, ll. 60-66 & Figs. 4, 5 & 9. In other words, the depth of the slit that receives the threaded rod is selected such that there is a gap, and not any “compression member,” between the bottom of the rod and the top surface of the screw. Thus, the premise of Alphatec’s argument (as disclosed in its answer to DePuy’s interrogatory) fails at the outset because the inventors of the ‘678 patent did not distinguish the “compression member” of their invention from a prior art member. Furthermore, neither the description of this device in the ‘678 patent nor the ‘458 patent so much as mention the direction of the forces exerted onto the pedicle screw. *See* ‘678 patent, col. 1, ll. 34-45; *see also* ‘458 Patent, col. 5, ll. 8-16 (fastening screws may be tightened to achieve either a substantially stiff connection or a connection that permits a desired dampened movement).

As nearly as may be understood, Alphatec appears to contend that because (a) “non-vertical” forces were at work in the ‘458 device (although no such forces are described) and (b) the inventors of the ‘678 patent described a shortcoming of the ‘458 device (although not one related to the direction of compressive forces), then (c) the term “compression member” in the ‘678 patent should be restricted to a component that does not impart any “non-vertical” forces.

² Specifically, both EP 0 242 708 and the ‘458 patent claim priority to a German patent application, DE 3614101, filed on April 25, 1986.

This is more than an impermissible attempt to read a limitation from the specification into the claims, it is an attempt to read a limitation from *beyond* the specification into the claims. Unsurprisingly, there is no law to support such a reading.

A disclaimer of claim scope in the specification must be clear and explicit. *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d at 1374 (“[W]ords or expressions of manifest exclusion or explicit disclaimers in the specification are necessary to disavow claim scope.” (internal quotation marks omitted)). In *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, the Federal Circuit rejected an argument that a discussion of the prior art in a patent specification limited the scope of the claims. 473 F.3d 1173 (Fed. Cir. 2006). The technology at issue in *Ventana* related to automated systems for preparing slides for pathological assessment. *Id.* at 1176. The claim limitation at issue was “dispensing,” which the district court had construed to require that the reagent be dispensed directly from the reagent container onto the slide, rather than by means of a pipette or other intermediate device (also known as “sip and spit”). *Id.* at 1178.

The *Ventana* court examined the words of the claim and observed that “claims 1 and 5 do not contain any language that could be read to limit the term ‘dispensing’ to mean ‘direct dispensing.’” *Id.* Likewise in this case, nothing in the claims of the ‘678 patent suggests that “compression member” is limited to a component that imparts no lateral force and nothing but “vertical” force.

The *Ventana* court then addressed the defendant’s argument based on the specification. Like Alphatec in this case, the defendant, BioGenex, asserted that a discussion of prior art in the specification limited the scope of the claims:

BioGenex argues that the patent’s specification compels a narrow construction of “dispensing.” BioGenex first points to the “BACKGROUND ART” section of the patent, which discusses a number of prior art automated staining devices, including a device that BioGenex alleges employs the “sip and spit” method of dispensing. 861 patent, col. 2, ll. 6-16. BioGenex argues that because the patent goes on to state that “[t]he previously known devices are limited in their performance and unable to satisfy the needs for automated, high precision immunohistology” and that it was an object of the invention to “provide a device which provides more rapid, reliable and more reproducible results than standard

methods,” *id.* at col. 2, ll. 26-31, the patent makes clear that the invention does not practice the “sip and spit” method of dispensing.

Id. at 1180. The *Ventana* court rejected BioGenex’s argument:

BioGenex points to only general statements by the inventors indicating that the invention is intended to improve upon prior art automated staining methods: “The previously known devices are limited in their performance and unable to satisfy the needs for automated, high precision immunohistology. It is an object of this invention to provide a device which provides more rapid, reliable and more reproducible results than standard methods” 861 patent, col. 2, ll. 26-31. Such general statements, without more, will not be interpreted to disclaim every feature of every prior art device discussed in the “BACKGROUND ART” section of the patent.

Id. at 1181 (emphasis added); *see also Brookhill-Wilk, I, L.L.C. v. Intuitive Surgical Inc.*, 334 F.3d 1294, 1300-02 (Fed. Cir. 2003) (statements in specification regarding background and objectives of invention did not limit the claims).

The reasoning of *Ventana* applies in this case. The discussion to which Alphatec points appears in the first column of the specification of the ‘678 patent and generally identifies the problem of high stocking costs. The specification does not identify any other disadvantage of the ‘458 device; to the contrary it states, “[t]his provides a very well operating pedicle screw.” ‘678 Patent, col. 1, ll. 44-45. This does not amount even to a criticism of the operation of the ‘458 device, let alone an explicit disclaimer of claim scope. Alphatec’s attempt to rewrite the ordinary meaning of “compression member” should be rejected.

B. “Spherically-Shaped” Means *Approximately Spherical, Such As A Globe Or Basketball*

In the *Medtronic* case, this Court construed “spherically-shaped” to mean “approximately spherical, such as a globe or basketball.” (Ex. 3 at 5). For the reasons explained in the Court’s claim construction order in the *Medtronic* litigation (Ex. 3 at 4-7), this is the correct construction.

Alphatec apparently disagrees. In its responses to DePuy’s interrogatories, Alphatec states:

Under the doctrine set forth, *inter alia*, in *Wilson Sporting Goods*, the claims of the ‘678 patent cannot be construed to cover the devices disclosed in the prior art including U.S. Patent Nos.

5,474,555 (“the ‘555 patent”) and 5,360,431 (“the ‘431 patent”). Thus, the term “inner hollow spherically-shaped portion (9)” cannot be construed to cover a housing having a feature such as elements 42 and 44 disclosed in the ‘555 patent but must be construed to mean a spherical feature such as disclosed in Fig. 2 of the ‘678 patent.

Alphatec 3d Supp’l Resps. to Interrogs. (Ex. 5) at 2-3. Alphatec’s reliance on *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.* 904 F.2d 677, 683 (Fed. Cir. 1990) is misplaced. That case does not address a limitation on claim construction; rather, it addresses the consequence of a claim construction that reads on prior art upon the application of the doctrine of equivalents (*i.e.* “ensnarement”). Consequently, *Wilson Sporting Goods* is of no relevance for purposes of claim construction.³

In short, this Court’s prior construction of “inner hollow spherically-shaped portion” reflects the understanding of a person of ordinary skill in the art, and Alphatec’s argument that it should be altered in light of *Wilson Sporting Goods* and the Puno ‘555 patent should be rejected.

C. The Court Is Bound By The Federal Circuit’s Claim Construction Of “Pressed Against A Hollow-Spherically-Shaped Portion”

The Federal Circuit has concluded that the term “‘hollow spherically-shaped portion’ includes the edge of that portion and that the screw head is ‘pressed against’ the ‘hollow spherically-shaped portion’ if it presses against all or any part of that portion—including the edge.” *DePuy Spine, Inc.*, 469 F.3d at 1014-15 (Fed. Cir. 2006). That determination is binding on this Court. *See Amgen*, 494 F. Supp. 2d at 60.

D. The Court Should Adopt Its Previous, Well-Reasoned Construction Of “Flexibly Connected”

In the *Medtronic* litigation, the Court construed “flexibly connected” to mean “that the screw head and receiver member [be] joined together in a flexible manner such that the screw assembly has the ability to bend at the connection between the screw head and the receiver.”

³ Alphatec’s argument will fail on the merits in any event. First, the Alphatec device is accused of literal infringement (to which the ensnarement doctrine does not apply). Second, assuming infringement by equivalents ultimately did become an issue in this case, this Court addressed, and rejected, Medtronic’s arguments under *Wilson Sporting Goods* with respect to the Puno ‘555 patent, which has an identical disclosure to the ‘431 patent, in the Court’s order of December 11, 2007, in case number 01-cv-10165 (attached as Ex. 6).

(Ex. 3 at 13.) This refers to the polyaxial nature of the device – the screw head can pivot in the receiver. (*Id.* at 10.) Alphatec has not come forward with any new argument to dispute this construction. Accordingly, it is binding in this matter as well. *See Amgen*, 494 F. Supp. 2d at 60.

E. The Court Has Already Construed The Term “Holes For Receiving A Rod” In This Case

After extensive briefing in connection with Alphatec’s unsuccessful motion for summary judgment of non-infringement, the Court construed “holes for receiving a rod” to mean “openings which include U-shaped slits.” (Ex. 3 at 3, 6.) That ruling should not be disturbed.

III. CONCLUSION

For all of the foregoing reasons, the Court should enter an order restating its previous claim constructions and those of the Federal Circuit.

Dated: March 10, 2008

Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of March, 2008, this document was served by e-mail, pursuant to the parties' agreement, to:

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